## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SANDRA BILLECI, et al. : CIVIL ACTION

:

V.

:

MERCK & CO., INC., et al. : NO. 17-486

## MEMORANDUM

Bartle, J. April 5, 2018

Plaintiff Sandra Billeci and her husband Dennis Billeci have sued defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively "Merck") for personal injuries arising out of Sandra Billeci's receipt of the Zostavax vaccine for the prevention of shingles. Merck is alleged to have manufactured, marketed, and distributed Zostavax. Ms. Billeci brings claims for negligence, design defect, failure to warn, breach of express warranty, and breach of implied warranty. Her husband has a claim for loss of consortium. Defendants have now moved for summary judgment under Rule 56 of the Federal Rules of Civil Procedure on the ground that the action is barred by the applicable statute of limitations.

Ι

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 323

(1986). A dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986). Summary judgment is granted where there is insufficient record evidence for a reasonable factfinder to find for the nonmovant. Id. at 252.

ΙI

We must first determine the proper limitation period for each count.

Ms. Billeci received the vaccine in the state of California where both she and her husband reside. Because this diversity action is pending in the United States District Court for the Eastern District of Pennsylvania, we must look to the choice of law rule of the underlying forum, that is the Commonwealth of Pennsylvania. Klaxon Co. v. Stenton Elec. Mfg. Co., Inc., 313 U.S. 487 (1941). Under Pennsylvania's Uniform

<sup>4.</sup> Rule 56(c)(1) of the Federal Rules of Civil Procedure states:

A party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or . . . showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

Statute of Limitations on Foreign Claims Act, "The period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim." 42 Pa. Cons. Stat. § 5521(b). Thus, for each count, the relevant shorter statute of limitations governs.

For the personal injury counts sounding in tort, both California and Pennsylvania have a two year limitations period. Cal. Civ. Proc. Code § 335.1; 42 Pa. Const. Stat. § 5524. In California, breach of warranty claims arising from the sale of goods are typically subject to a four-year statute of limitations. Cal. Com. Code § 2725. However, the two-year limitations period governing tort claims applies instead when, as here, the breach of warranty involves a personal injury. Cal. Civ. Proc. Code § 335.1; Rivas v. Safety-Kleen Corp., 119 Cal. Rptr. 2d 503, 513-14 (Ct. App. 2002); Becker v. Volkswagen of Am., Inc., 52 Cal. App. 3d 794, 802 (1975). Pennsylvania's limitations period for breach of warranty is four years. 13 Pa. Const. Stat. § 2725. Since we must always apply the shorter deadline, the applicable time-bar here for all counts, both in tort and contract, is two years.

In considering the defendants' motion for summary judgment, we must view the facts in the record in the light most favorable to the plaintiffs.

Ms. Billeci received the Zostavax vaccine ("the shingles vaccine") on September 15, 2014 at a Kaiser Permanente ("Kaiser") facility in Vallejo, California. Less than a month later, on October 9, 2014 she contacted by telephone Dr. Irina Rozen, a physician at the Kaiser facility. Dr. Rozen recorded in her log that Ms. Billeci complains of "'strange sensations all over body' - feels like skin hypersensitivity - 'skin is too sensitive' intermittent and various places." Dr. Rozen noted that Ms. Billeci had received the shingles vaccine three to four weeks ago. She diagnosed Ms. Billeci with "tingling sensation."

A month and a half later, on November 24, 2014,

Ms. Billeci visited Dr. Rozen at her office. Dr. Rozen's notes
of the visit show that Ms. Billeci had a "chief complaint of skin
problem" and that she "complains about itchy skin[,]" "mainly
[on] legs and arms[,]" which is "[m]uch better [t]oday." Ms.
Billeci remembered asking Dr. Rozen on this date if the shingles
vaccination was related to her problems of itchy skin. Dr.
Rozen's response to this question is not contained in the record.
She diagnosed Ms. Billeci with pruritus, which she described in
her deposition as itchiness of the skin.

Ten days later, Ms. Billeci spoke with Dr. Rozen on the phone. Ms. Billeci complained of continued "itching/slight prickling all over her body - describes 'as if she has a wool sweater on.'" Dr. Rozen's notes reveal that laboratory tests previously performed on Ms. Billeci revealed no rash and the source of the itching was unclear. Dr. Rozen prescribed Doxepin for the itchiness. She noted that Ms. Billeci was "slightly neutropenic," meaning that she had a slightly low white blood cell count. Ms. Billeci recalled telling Dr. Rozen that she wondered if the shingles vaccine was the reason she was experiencing the itchiness.

Ms. Billeci spoke with an internal medicine specialist from Kaiser, Dr. Robert Quon, over the telephone on December 19, 2014. In his record, Dr. Quon described Ms. Billeci as a patient "with migratory pruritus that followed [her] Zoster vacc[ine]." During the call, Ms. Billeci described her symptoms as a "sensation of hypersensitivity and itching" and explained that they are "better when [she wears] lightweight clothing . . . [and] use[s] Doxepin[.]"

Later that month on December 30, 2014 Ms. Billeci consulted Dr. Emerita Natividad Brigino-Buenaventura of Kaiser by phone. Dr. Brigino-Buenaventura's observations of the encounter

<sup>2.</sup> The date that the laboratory tests were performed is unclear. Dr. Rozen stated in her deposition that she ordered the tests on November 21, 2014.

show that Ms. Billeci had experienced eight weeks of "[h]eightened nerve sensitivity - pinprick sensation all over body." Dr. Brigino-Buenaventura's notes document that Ms.

Billeci received the shingles shot on September 15, 2014 and that Ms. Billeci reported to Dr. Brigino-Buenaventura that she may have felt the pinprick sensation at "about that time." According to the notes, the sensations "seem to be waxing and waning[.]" Dr. Brigino-Buenaventura diagnosed Ms. Billeci with abnormal skin sensitivity and noted "could be adverse effect from ZOSTER VIRUS Live vaccine[.]" Significantly, Dr. Brigino-Buenaventura told Ms. Billeci that the vaccine could be the cause of her abnormal skin sensitivity and that symptoms usually wane over time. She prescribed Ms. Billeci Doxepin.

On January 22, 2015 Ms. Billeci called Dr. Rozen and left a message with a nurse stating that she wanted to "talk . . . about [her] chronic reaction to shingles." According to the message, Ms. Billeci had "looked it up on the internet" and felt that she was having a reaction to the vaccine. While Ms. Billeci does not remember telling the nurse, she remembers having looked up information about the shingles vaccine on the internet. When asked in her deposition whether remembered reporting to the doctor's office that she had looked up information on the internet and if she had found anything about a chronic reaction to the vaccine, she responded: "I did look for things on the

internet about [the] shingles vaccination, and . . . I could not find anything other than what I was told at that time that said you could have what I had. I never could find anything. It's always been my personal conviction, you know."

Four days later Ms. Billeci again spoke with Dr. Quon over the phone about her symptoms. In his record, Dr. Quon recounted that Ms. Billeci's rash and prickling sensation developed a few weeks after she received the Zostavax shot. Dr. Quon diagnosed her with peripheral neuropathy. His notes acknowledge that Ms. Billeci "thought she may be having [problems] with post herpetic neuralgia, but [patient] never had flare of Zoster. Advised her pin prickly sensation is likely an idiosyncratic [reaction] due to her vacc[ination] and may wane in time. The patient indicates understanding of these issues and agrees with the plan." Ms. Billeci does not recall telling Dr. Quon that she had a rash and does not recall suggesting that she had post herpetic neuralgia because, "I didn't know that word so I did not tell him that."

Ms. Billeci was asked in her deposition when she decided that she wanted to bring a lawsuit. She responded: "In

<sup>3.</sup> Peripheral neuropathy is "damage to the peripheral nervous system which transmits information from the brain and spinal cord to every other part of the body." Symptoms include pain, numbness, tingling feeling, prickling sensations, sensitivity to touch, and muscle weakness. See U.S. National Library of Medicine, PubMed Health Peripheral Neuropathy, https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0029729/.

my mind, in January [of 2015] I tried to find some help. . . . I reported it to different places."

On January 23, 2015 Ms. Billeci contacted Kaiser to request compensation from Kaiser due to the "adverse side effects of a shingles vaccine [she] received at the Kaiser Permanente Vallejo Medical Center . . . on September 15, 2014." It appears that this request was made orally since the record does not contain any written record of the request itself. The request is documented by a January 28, 2015 letter from Kaiser to Ms. Billeci that was sent in response to her request. The letter informed her that the request had been received and it would be evaluated.

A few weeks later, on February 9, 2015, Ms. Billeci submitted an adverse event report to the Vaccine Adverse Event Reporting System ("VAERS") to the Centers for Disease Control and Prevention and the United States Food and Drug Administration.

In the VAERS report, Ms. Billeci described the adverse event being reported as: "I first had little pin prick pains on different areas of body. Maybe 4 or 5 a day. In about 2 weeks cronic [sic] prickling, tingling, burning and some stabbing pain started. This pain has been going on now ever since. Some days a [sic] better than others. . . . I am taking Doxepin 2 10 milligram capsules." She stated that she was previously administered the shingles shot and a steroid shot in her knee.

Additionally, she reported that the onset date of the event was September 17, 2014.

Ms. Billeci's January 23, 2015 request for compensation. It acknowledged that she had reported that she experienced side effects from the shingles vaccine that she received on September 15, 2014. In addition, it confirmed that Ms. Billeci stated that neither Dr. Rozen nor the Kaiser licensed nurse who administered the vaccine apprised her of the potential side effects prior to the vaccination and they had not determined the cause of her symptoms. Kaiser advised that it had "carefully reviewed [her] records and other relevant information to come to our decision and we are denying your request."

In the February 21, 2015 letter, Kaiser explained that on behalf of the Chief and Director of the Adult Medicine for the Vallejo Medical Center, the Assistant Chief reviewed her concerns and advised "that based on the literature currently available for the shingles vaccination, the only side effects are a local rash and sensation of heat and itchiness." Kaiser provided her with contact information for its legal department and ultimately denied her request for compensation "because it is a non-medical expense and, as such, is not a covered Health Plan Benefit."

Ms. Billeci does not remember seeing any doctors between March 2015 and November 2015 for her symptoms of skin

itchiness. On November 9, 2015 Ms. Billeci reconnected with the doctors at Kaiser by emailing Dr. Brigino-Buenaventura with the email subject line of "pringling from shingles shot." Ms.

Billeci's email expressed her concern over the pringling, asking "[D]o you think this is ever going to get better or go away? I get discouraged every day [sic] is different." She asked whether her Doxepin medication could now be ineffective and asked to be prescribed a different medication, Gabapentin, that her friend told her about. In response, Dr. Brigino-Buenaventura instructed Ms. Billeci to contact Dr. Rozen.

Seven months later, on July 19, 2016, Ms. Billeci emailed Dr. Rozen, including the subject line of "Neuropathy from shingles shot." Ms. Billeci wrote, "[L]awyers are starting to recognize that people have had reactions from the shingles shot. [I]n order for me to get help I have to have a diagnosis of neuropathy. . . . I am trying to find out if I have this diagnosis[.]" Dr. Rozen responded the following day, telling her that her medical record notes that she had symptoms of peripheral neuropathy. Dr. Brigino-Buenaventura confirmed to Ms. Billeci that these descriptions were in her medical records.

Ms. Billeci and her husband filed the instant action on February 2, 2017.

As noted above, Ms. Billeci was administered the Zostavax vaccine on September 15, 2014. This lawsuit was not filed until February 2, 2017, some two years and four and one-half months later. Generally, under both California and Pennsylvania law, the statute of limitations begins to run when the claim accrued, that is when the injury is inflicted or the disease commences. Fine v. Checcio, 870 A.2d 850, 857 (Pa. 2005); Fox v. Ethicon Endo-Surgery, Inc., 110 P.3d 914, 919 (Cal. 2005). While the action was commenced outside the two year limitations period, plaintiffs contend that it was timely nonetheless under the discovery rule. Fine, 870 A.2d at 858; Fox, 110 P.3d at 919.

Both Pennsylvania and California adhere to the discovery rule which provides that the statute of limitations is tolled when a plaintiff does not know or does not have reason to know, through the excuse of reasonable diligence, of his or her injury. The Pennsylvania Supreme Court explained:

Reasonable diligence is just that, a reasonable effort to discover the cause of an injury under the facts and circumstance present in the case. Long ago we

<sup>4.</sup> Pennsylvania does not apply the discovery rule to claims for breach of express warranty or breach of implied warranty. 13 Pa. Con. Stat. § 2725; Speicher v. Dalkon Shield Claimants Trust, 943 F. Supp. 552, 554 (E.D. Pa. 1996); Northampton Cty. Area Cmty. Coll. v. Dow Chem., U.S.A., 566 A.2d 591, 599 (Pa. Super. Ct. 1989). This is not of concern here since the Pennsylvania statute of limitations is not applicable in light of the shorter California limitations period.

recognized that 'there are a few facts which diligence cannot discover, but there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful. This is what is meant by reasonable diligence.'

Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995) (citing Deemer v. Weaver, 187 A. 215, 217 (Pa. 1936)). The rule is similar in California. See Jolly v. Eli Lilly & Co., 751 P.2d 923, 926-27 (Cal. 1988). While the defendant has the burden of proof to establish that the statute limitations has run, the burden of proof is on the plaintiffs to establish that the discovery rule applies and that the time for bringing suit has been tolled.

Cochran, 666 A.2d at 249; e.g., William L. Lyon & Assocs., Inc. v. Superior Court, 139 Cal. Rptr. 3d 670, 681-82 (Cal. Ct. App. 2012).

A plaintiff does not have to have a definitive diagnosis of any injury for the statute to run: "unrebutted suspicion that a claimant has a particular disease, which is caused by another, is sufficient to start the clock." <u>Debiec v.</u>

<u>Cabot Corp.</u>, 352 F.3d 117, 132 (3d Cir. 2003); <u>see also Fox</u>,

110 P.3d at 919. The suspicion can be rebutted and the statute is tolled where a plaintiff reasonably relies on the assurance of her physician or health care provider that her suspicion about the cause of the injury or disease is unfounded. <u>Debiec</u>, 352

F.3d at 132. If it at some point it becomes no longer reasonable

to rely on the assurance of the physician or health care provider, the clock, of course, again begins to run its course.

Id. We have found no California case and none has been cited which is inconsistent with this logical analysis in Debiec.

Whether a plaintiff exercised reasonable diligence to discover the cause of her injury is generally a jury question.

Fine, 870 A.2d at 858-59; e.g., Cleveland v. Specialties West,

Inc., 88 Cal. Rptr. 3d 892, 897-98 (Cal. Ct. App. 2009). Only where the facts are so clear that reasonable minds cannot differ is the issue for the court to decide. Cochran, 666 A.2d at 248.

The record can certainly be read that virtually from the outset Ms. Billeci had a reasonable suspicion that the Zostavax vaccine was the cause of her injuries at least up until she received the February 21, 2015 letter from Kaiser. Up until that time, Ms. Billeci continually contacted Dr. Rozen and Dr. Brigino-Buenaventura of Kaiser expressing concern that the tingling and itching sensations she was experiencing were not improving and suggesting that they were related to the shingles vaccine. The record reflects that Ms. Billecci contacted Dr. Rozen, Dr. Brigino-Buenaventura, or Dr. Quon on seven occasions complaining of her symptoms and referencing the shingles vaccine in one way or another.

Significantly, she has testified that as of late

January 2015 "it's always been my personal conviction" that her

illness was connected to the Zostavax vaccine. As noted above, Ms. Billeci contacted Kaiser on January 23, 2015. She blamed it for not warning her about the potential for harm from her vaccination and seeking compensation due to "adverse side effects of a shingles injection . . . [she] received at Kaiser Permanente Vallejo Medical Center Medical Department on September 15, 2014."

In Kaiser's response dated February 21, 2015, it denied her request for compensation. The letter assured her, "we have carefully reviewed your records and other relevant information." The Kaiser letter confirmed that she had "shared [her] concerns regarding the side effects of the shingles vaccination [she] received on September 15, 2014." Significantly, the letter then informed her:

Your concerns have been forwarded to the Chief and Director of Adult Medicine for the Vallejo Medical Center for research and response. The Assistant Chief has responded on behalf of the Chief. He has advised that based on the literature currently available for the shingles vaccination, the only side effects are a local rash and sensation of heat and itchiness. (emphasis added)

At her deposition, Ms. Billeci testified that before receipt of this letter she always suspected that the Zostavax vaccine had caused her injury. However, once she received the letter, her view changed. She now understood Kaiser as assuring her that there was no causal connection. The letter based its conclusion on her medical records at Kaiser, on the opinion of

the top physician in the field of adult medicine at Vallejo Medical Center, and on medical literature on the subject of shingles vaccination.

It is certainly reasonable to read the letter as telling Ms. Billeci that there can be no adverse effects from an injection of Zostavax vaccine other than "a local rash and sensation of heat and itchiness." Ms. Billeci, of course, is claiming much more serious injuries than these. The evidence is sufficient for the finder of fact to decide that Ms. Billeci reasonably relied on Kaiser's representations so as to extinguish her suspicions about causation.

Defendants contend that Ms. Billeci did not exercise reasonable diligence in uncovering the cause of her injury since she did not follow up with the legal department of her healthcare provider, Kaiser Foundation Health Plan, Inc., after she received the February 21, 2015 letter from it. It is highly unlikely that any contact with Kaiser's legal department - as opposed to a lawyer she engaged - would have reawakened her suspicions.

Notwithstanding the letter, defendants also point to evidence that plaintiffs suspected a causal connection between the Zostavax vaccine and her injuries thereafter on November 9,

<sup>5.</sup> Ms. Billeci claims in her complaint that she had been experiencing prickling of her legs and feet, stabbing pains in her abdomen, and muscle stiffness. She asserts that she has been diagnosed with postherpetic neuralgia and damage to her central nervous system.

2015. On this date Ms. Billeci sent an email to

Dr. Brigino-Buenaventura at Kaiser which had the subject line of "pringling from shingles shot." There is additional evidence of Ms. Billeci's suspicions after November 9, 2015, culminating, of course, in filing of this lawsuit on February 2, 2017. Even so, there remains a hiatus of over eight months between Kaiser's February 21, 2015 letter to Ms. Billeci and her November 9, 2015 email to Dr. Brigino-Buenaventura. Ms. Billeci did not contact a physician during this period. Defendants have not referenced any relevant evidence that during this time frame Ms. Billeci no longer reasonably relied on the representations in the February 21, 2015 letter.

This action was filed approximately two years and four and one-half months after she received the vaccine. If the two year statute of limitations is tolled for approximately eight months, that is between late February and early November 2015, the action would still be timely. With the tolled period of eight months excluded, the clock was running for less than two years between the time she was vaccinated with Zostavax and the date she filed her lawsuit.

The facts are not so clear here that reasonable minds cannot differ. Genuine disputes of material fact exist. Based on the present record, the court cannot rule in defendants' favor as a matter of Pennsylvania or California law on their motion for

summary judgment. It will be for the jury to decide whether plaintiffs can prove that Ms. Billeci's original suspicion about Zostavax being the cause of her injuries reasonably ceased and for a sufficient period of time as a result of Kaiser's February 21, 2015 letter. Thus it will be for the jury to determine whether plaintiffs have established the facts necessary for the application of the discovery rule and equitable tolling so that this action may proceed to a trial on the merits.

V

Finally, plaintiffs argue that fraudulent concealment on the part of the defendants about the effect of the Zostavax vaccine has also tolled the statute of limitations. This argument is without merit as plaintiffs have not identified any supporting facts in the record. See Perelman v. Perelman, 545 F. App'x 142, 150 (3d Cir. 2013); Yumul v. Smart Balance, Inc., 733 F. Supp. 2d 1117, 1123 (C.D. Cal. 2010).

VI

Accordingly, the motion of defendants for summary judgment on the ground that the statute of limitations bars this action will be denied.